510(k) Summary

APR 16 2014

Sponsor: Sterngold Dental, LLC
23 Frank Mossberg Drive
Attleboro, MA 02703

Contact: Maria Rao, QA/RA Director
Ph: 508-226-5660 ext 1206

Trade Name: ORA Implant Abutments System

Common Name: Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II

Product Code: NHA (21CFR 872.3630)

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):
Predicate Device(s): K900099, K130183, K132814.

K900099	The O-Ring System – ORS
K130183	SFI Bar® Implant Abutments for 7 Platforms
K132814	SFI Bar® Implant Abutments for 9 Platforms

Description of Device:
The ORA Implant Abutment is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring.
The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier. The bottom portion of the abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183 and K132814.
ORA Implant Abutments are available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 and K132814– SFI Implant Abutments.

The devices are supplied non-sterile, and there is no shelf life.

Intended Use of the Device:
The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

Implant Brand	Model
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE™ Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE™ Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE™ Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain™, 4.0 OSSEOTITE® NTCertain™, 4.O OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ™	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental	3.5 Bio-Vent® X™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head),4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
Straumann	ITI TE™ 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE™ 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

Technical Characteristics:
The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

Attribute	Candidate	Predicate Device	Predicate Device
	The ORA Implant Abutment Sterngold Dental, LLC	**The O-Ring System – ORS Attachments International, Inc. K900099**	**SFI Implant Abutments Sterngold Dental, LLC K130183, K132814**
Design/Construction	Machined, screw-retained	Machined, screw-retained	Machined, screw-retained
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Device Material	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy
Indications for Use	Indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.	The ORS Implant Abutments are intended for use with dental implants as a support or attachment for prosthetic restoration. The abutment screws directly into the implant.	The SFI-Bar® Implant Abutments are indicated for use with dental implant bodies/fixtures to support and /or retain removable dental prostheses for partially or totally edentulous patients to restore chewing function.
Operating Principle/ Basic Design	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture
Packaging, materials and processes	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile
Cuff Sizes	0.4, 1.0, 1.25, 2.0, 3.0, 4.0, 5.0mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0mm	1.0, 1.5,1.75, 2.0, 2.2, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5mm
Prosthetic Connection	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head

Performance Date:
Application and functional testing have been conducted to evaluate the performance characteristics of the ORA Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the ORA Implant Abutments included in this application are equivalent in performance characteristics to its predicate devices.

Safety and Effectiveness / Conclusion:
Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of tolerance analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The summary of technological characteristics as well as application and functional testing indicate that the device is substantially equivalent to the declared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 16, 2014

Sterngold Dental, LLC
Ms. Maria Rao
Director, Quality and Regulatory Affairs
23 Frank Mossberg Drive
Attleboro, MA 02703

Re: K133791
Trade/Device Name: ORA Implant Abutments System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 17, 2014
Received: March 19, 2014

Dear Ms. Rao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K133791

Device Name: **ORA Implant Abutment System**

Indications for Use:

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Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw. 4.2 Sustain® External Hex MC Cylinder. Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE™ Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE™ Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE™ Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain™, 4.0 OSSEOTITE® NTCertain™, 4.O OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ™	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental	3.5 Bio-Vent® X™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head),4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
Straumann	ITI TE™ 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE™ 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm

	ScrewPlant
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ (Part 21 CFR 801 Subparts D) AND/OR Over-the -Counter Use ____ (21 CFR 807 Subpart D)

Sheena A. Green -S
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